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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,425	07/06/2001	Hongjiang Wu	ISPH-0522	7138

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/900,425	Applicant(s) WU ET AL.	
	Examiner Sean R McGarry	Art Unit 1635	

-- The MAILING DATE of this communicati n appears on the cover sheet with the c rrespondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

SEAN McGARRY
PRIMARY EXAMINER

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 19, drawn to a RNase III protein and compositions comprising RNase III protein, classifiable in class 530, subclass 350.

II. Claims 5-10, drawn to nucleic acid encoding RNase III, classifiable in class 536, subclass 23.1.

III. Claim 11, drawn to antibodies targeted to an RNase III protein, classifiable in class 530, subclass 387.1.

IV. Claim 12, drawn to a probe to RNase III, classifiable in class 536, subclass 24.31.

V. Claims 13 and 14, drawn to antisense oligonucleotides targeted to and RNase III encoding nucleic acid, classified in class 536, subclass 24.5.

VI. Claim 16, drawn to a method of inhibiting RNase III expression via antisense, classifiable in class 514, subclass 44.

VII. Claim 17, drawn to a method of inhibiting RNase III activity via antibodies, classifiable in class 514, subclass 2.

VIII. Claims 18 and 36, drawn to a method of identifying agent which increase or decrease activities or levels of RNase III in a host cell, classifiable in class 435, subclass 7.1.

IX. Claims 20-28 and 37-47, drawn to a method of promoting inhibition or expression of a selected protein via antisense, classifiable in class 435, subclass 375.

X. Claims 29-34, drawn to a method of screening oligonucleotides to identify effective antisense oligonucleotides for inhibition of expression of a selected protein, classifiable in class 514, subclass 44.

XI. Claim 35 , drawn to a method of prognosticating the efficacy of an antisense therapy via the measure of RNase III in a cell, classifiable in class 435, subclass 7.1.

XII. Claims 48-52, drawn to a method of promoting RNA interference in a cell via the enrichment of RNase III in the cell, classified in class 514, subclass 44.

Claim 15 link(s) inventions VI and VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group V is furthersubject to the following:

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the antisense sequences listed in claim 14 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Claim 14 specifically claims antisense SEQ ID NOS 8-15, which are targeted to and inhibits the expression of RNase III. Although the antisense sequences claimed each target and modulate expression of the same gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of the gene, and each antisense, upon binding to the gene sequence, functionally modulates (increases or decreases) the expression of the gene and to varying degree (per applicants' Table 1 in the specification). Furthermore, a search of more than one (1) of the antisense sequences claimed in claim 14 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a

reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) antisense sequence from claim 14 for examination.

The inventions are distinct, each from the other because of the following reasons:

Inventions VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods that each include the use of materially different components and each include different method steps where the different components used in the different method steps of the different methods result in different ends, for example.

Inventions I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different compounds that have different functions and or effects, for example. Group I is drawn to protein that may be used in a method to facilitate cleavage of a target nucleic acid, the nucleic acid of group II could be used to produce a protein and may be used in an in situ localization assay, the antibodies of Group III can be used to localize a specific protein, the probe of Group IV can function to as aprobe in a Northern blot, and the antisense of Group V functions to inhibit the activity of a specific protein, for example.

Inventions I and (VI-XII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group I could be used in a various methods as is evidenced by the use of the protein in various methods (which have been shown to be unrelated above) included in Groups VI-XII or the protein is not used in the method rendering the method and the protein mutually exclusive, for example.

Inventions II and VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of Group II could be used in a various methods as is evidenced by the use of the nucleic acid in various methods (which have been shown to be unrelated above) included in Groups VI-XII or the nucleic acid is not used in the method rendering the method and the nucleic acid mutually exclusive, for example.

Inventions III and VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group III could be used in a various methods as is evidenced by the use of the antibody in various methods (which have been shown to be unrelated above) included in Groups VI-XII or used in a method such

as an in situ localization assay or the antibody is not used in the methods of the Groups above rendering the method and the antibody mutually exclusive, for example.

Inventions IV and VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the probe of Group IV could be used in a various methods as is evidenced by the use of the probe in various methods (which have been shown to be unrelated above) included in Groups VI-XII or the probe could be used in a Norther Blot assay or the protein is not used in the methods of Groups VI-XII rendering the method and the probe mutually exclusive, for example.

Inventions V and VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antisense of Group V is not used in the methods of Groups VI-XII rendering the methods and the antisense mutually exclusive, for example.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SEAN McGARRY
PRIMARY EXAMINER
1635

SRM
August 28, 2002